

What is claimed is:

1. A method for assembling a stent loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft having a distal region and a lumen therethrough, a retractable sheath disposed over said shaft, a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow axially receiving said stent between said shaft and said sheath;

providing means for securing a distal tip to said shaft distal region;

axially sliding said stent proximally over said shaft distal region and within said sheath lumen; and

securing said distal tip to said inner shaft distal region.

2. A method for assembling a stent loaded, self-expanding stent delivery catheter as recited in claim 1, wherein said distal tip has a maximum outside diameter and said sheath has an inside diameter not greater than said distal tip outside diameter, such that said stent cannot fit over said distal tip when constrained to fit within said sheath.

3. A method for assembling a stent loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow axially receiving said stent between said shaft and said sheath, said shaft having a distal region and a distal end, said sheath having a distal region and a distal end, said stent having a distal end;

providing a shrinkable film material;

providing a distally decreasing tapered tip having a lumen therethrough and a proximal end;

affixing a portion of said shrinkable film material to said shaft at a position in said shaft distal region proximal of said distal end such that there exists a free portion of said film distal of said affixed position;

positioning said sheath co-axially over said shaft such that said sheath distal end is positioned near said affixed film position;

positioning said compressed stent proximally and co-axially over said shaft such that said stent distal end is disposed near said affixed film position and said stent is radially constrained by said sheath distal region;

disposing said tip co-axially over said shaft such that said tip proximal end is positioned near said affixed film position;

draping at least some of said film free portion over said distal tip; and

shrinking said film free portion over said tip such that said tip is secured in place over said shaft by said shrunken film.

4. A method as recited in claim 3, wherein said sheath is positioned over said shaft before said stent is disposed within said sheath.

5. A method as recited in claim 3, wherein said film has a tubular shape having a proximal waist, wherein said affixing step includes bonding said waist to said shaft, and wherein said shrinking step includes heat-shrinking said film over said tip.

6. A method as recited in claim 3, wherein said shaft has outwardly directed projections in said distal region, wherein said film has a tubular shape having a proximal waist, wherein said affixing step includes snagging said waist on said shaft projections, and wherein said shrinking step includes heat-shrinking said film over said tip.

7. A loaded, self-expanding stent delivery catheter assembly comprising:  
a shaft having a distal end and a distal region;  
a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a tapered tip co-axially disposed over said shaft distal region substantially distally of said sheath distal region, said tip secured at least in part to said shaft by a film secured to said shaft distal region and secured to said tip.

8. A catheter assembly as recited in claim 7, wherein said film is shrink-fitted over said tip.

9. A catheter assembly as recited in claim 7, wherein said film has a tubular shape and a proximal waist and said waist is secured to said shaft distal region with bonding.

10. A catheter assembly as recited in claim 7, wherein said film has a tubular shape and a proximal waist, wherein said shaft distal region includes outwardly disposed projections, and wherein said film is secured to said shaft distal region by said projections catching on said film waist.

11. A loaded, self-expanding stent delivery catheter assembly comprising:

a shaft having a distal end and a distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a tapered tip co-axially disposed over said shaft distal region substantially distally of said sheath distal region, said tip secured to said shaft, wherein said tip has a maximum radial extent not less than the radial extent of said sheath distal region.

12. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow co-axially receiving said stent between said shaft and said sheath, said shaft having a distal region and a distal end with at least one outward projection in said distal region, said sheath having a distal region

and a distal end, said stent having a distal end;

providing a tapered tip having a lumen therethrough, a proximal region, and a proximal end;

positioning said sheath co-axially over said shaft such that said sheath distal end is positioned near said shaft distal region;

positioning said compressed stent proximally co-axially over said shaft such that said stent distal end is disposed near said shaft distal region and said stent is radially constrained by said sheath distal region;

disposing said tip co-axially over said shaft such that said tip proximal end is positioned near said shaft distal region; and

forcing said tip proximal region co-axially over said shaft outward projections such that said tip is caught on said projections and secured to said shaft.

13. A method as recited in claim 12, wherein said shaft outward projection has sharp outwardly extending edges and said tip proximal region includes an elastic wall and said forcing step includes stretching elastic wall over said sharp edges such that said edges cut at least partially through said elastic wall.

14. A method as recited in claim 12, wherein said tip proximal region lumen includes an internal recess adapted to received said shaft outward projection, said tip proximal region includes an elastic wall, and said forcing step includes stretching said elastic wall over said projection such that said projection extends into said internal recess.

15. A method as recited in claim 14, wherein said tip proximal internal recess is an annular channel and said projection is at least one annular ring and said forcing step includes forcing said elastic wall over said ring until said wall annular channel fits over said at least one annular ring.

16. A method as recited in claim 15, wherein said tip has a proximal region including a wall having at least one hole therethrough adapted to receive said shaft projection and said forcing step includes forcing said tip proximal region proximally over said projection and stretching said wall until said projections extends through said tip proximal region wall.

17. A method as recited in claim 16, where said tip includes a proximal waist and said hole through said wall is disposed in said waist.

18. A method as recited in claim 16, wherein said shaft outward projection includes at least on longitudinally oriented fin, said tip includes a proximal waist, said hole through said wall is disposed in said waist, said hole has a longitudinally oriented slot shaped to receive said fin, and said forcing step includes forcing said fin through said slot.

19. A loaded, self-expanding stent delivery catheter assembly comprising:  
a shaft having a distal end, a distal region, and at least one outwardly extending projection in said shaft distal region;

a retractable sheath having a distal region and a distal end disposed axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a distal tip co-axially disposed over said shaft distal region substantially distally of said sheath distal region, said tip secured to said shaft, wherein said tip has a proximal region wall and said tip is secured to said shaft by said projection extending into said tip proximal region wall.

20. A stent delivery catheter assembly as recited in claim 19, wherein said projection includes sharp edges and said edges cut into said tip wall.

21. A stent delivery catheter assembly as recited in claim 19, wherein said tip includes an internal recess receiving said projection.

22. A stent delivery catheter assembly as recited in claim 19, wherein said shaft projection includes a ring and said tip includes an internal annular recess receiving said ring projection.

23. A stent delivery catheter assembly as recited in claim 19, wherein said shaft projection includes a longitudinally oriented fin and said tip includes a

longitudinally oriented slot through said wall and said assembly has said tip secured to said shaft by said fin extending through said slot.

24. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, and a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow co-axially receiving said stent between said shaft and said sheath, said shaft having a distal region and a distal end, said sheath having a distal region and a distal end, said stent having a distal end;

providing a shrinkable film material;

providing a distal tip having a lumen therethrough and a proximal end;

affixing a portion of said shrinkable film material to said shaft at a position in said distal region proximal of said distal end such that there exists a free portion of said film distal of said affixed position;

positioning said sheath co-axially over said shaft such that said sheath distal end is positioned near said affixed film position;

positioning said compressed stent proximally and co-axially over said shaft such that said stent distal end is disposed near said affixed film position and said stent is radially constrained by said sheath distal region;

disposing said tip axially over said shaft such that said tip proximal end is positioned near said affixed film position;

draping at least some of said film free portion over said distal tip; and

shrinking said film free portion over said tip such that said tip is secured in place



over said shaft by said shrunken film.

25. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, and a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow co-axially receiving said stent between said shaft and said sheath, said shaft having a distal region and a distal end, said sheath having a distal region and a distal end, said stent having a distal end;

providing a polymeric sleeve;

affixing a portion of said polymeric sleeve to said shaft at a position in said distal region proximal of said distal end such that there exists a free portion of said polymeric sleeve distal of said affixed position;

positioning said sheath co-axially over said shaft such that said sheath distal end is positioned near said affixed polymeric sleeve position;

positioning said compressed stent proximally co-axially over said shaft such that said stent distal end is disposed near said affixed polymeric sleeve position and said stent is radially constrained by said sheath distal region;

disposing said tip axially over said shaft such that said tip proximal end is positioned near said affixed sleeve position; and

transforming said polymeric sleeve into a distal tip.

26. A method as recited in claim 25, wherein said distal tip has a maximum radial extent at least as large as the inside diameter of said stent in a constrained state.

FOOTNOTES

27. A method as recited in claim 25, wherein said polymeric sleeve includes a thermosetting material and said transforming step includes softening said polymeric sleeve, forming said sleeve into a tip shape, and hardening said tip.

28. A loaded, self-expanding stent delivery catheter assembly comprising:  
a shaft having a distal end, a distal region, and at least one outwardly extending projection in said shaft distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a distal tip co-axially disposed over said shaft distal region distally of said sheath distal region, said tip secured to said shaft, wherein said tip has a maximum radial extent greater than the inside diameter of said stent in a constrained state.

29. A catheter assembly as recited in claim 28, wherein said tip has a maximum radial extent greater than the inside diameter of said sleeve distal end.

30. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath and a self-expanding tubular stent, said

shaft, stent, and sheath cooperatively sized so as to allow axially receiving said stent between said shaft and said sheath, said shaft having a threaded distal region and a distal end, said sheath having a distal region and a distal end, said stent having a distal end;

providing a distal tip, having a threaded proximal region adapted to mate to said shaft distal threaded region and having a proximal end;

positioning said sheath co-axially over said shaft such that said sheath distal end is positioned near said shaft distal region;

positioning said compressed stent proximally co-axially over said shaft such that said stent distal end is disposed near said shaft distal region and said stent is radially constrained by said sheath distal region; and

threading said tip unto said shaft distal region such that said tip is secured to said shaft by said tip and shaft threads.

31. A loaded, self-expanding stent delivery catheter assembly comprising:

a shaft having a distal end, a distal region, and at least one outwardly extending projection in said shaft distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a distal tip co-axially disposed over said shaft distal region distally of said sheath

distal region, said tip secured to said shaft, wherein said shaft distal region has threads and said tip has threads adapted to mate to said shaft threads and said shaft and tip are threadably secured together.

32. An assembly as recited in claim 31, wherein said shaft threads are externally disposed and said tip threads are internally disposed.

33. A loaded, self-expanding stent delivery catheter assembly comprising:

a shaft having a distal end, a distal region, and a threaded distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a distal tip co-axially disposed over said shaft distal region distally of said sheath distal region, said tip secured to said shaft, said tip having a coil adapted to mate to said shaft threads, wherein said shaft and tip are secured together by said coil pressing against said threads.

34. An assembly as recited in claim 33, wherein said shaft threads are external.

35. An assembly as recited in claim 33, wherein said tip has a tip body formed as a coil.

36. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow axially receiving said stent between said shaft and said sheath, said shaft having a reversibly radially compressible distal tip having a maximum outside diameter, said sheath having a distal region and a distal end, said stent having a distal end and an inside diameter;

radially compressing said tip such that said maximum outside diameter is less than said stent inside diameter;

positioning said sheath co-axially over said tip and shaft such that said sheath distal end is positioned near said distal tip;

positioning said compressed stent proximally co-axially over said shaft such that said stent distal end is disposed near said distal tip and said stent is radially constrained by said sheath distal region; and

uncompressing said tip such that said tip maximum radial extent increases.

37. A loaded, self-expanding stent delivery catheter assembly comprising:

a shaft having a distal end, a distal region, and a threaded distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of

said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a reversibly radially compressible distal tip affixed to said shaft distal region.

38. A catheter assembly as recited in claim 37, wherein said sheath lumen distal region has a radial extent, said distal tip has an unconstrained maximum radial extent at least as large as said sheath lumen distal region radial extent, wherein said distal tip has a compressed maximum radial extent less than the inside diameter of said stent in a compressed state.

39. A method for assembling a loaded, self-expanding stent delivery catheter comprising the steps of:

providing a shaft, a retractable sheath, a self-expanding tubular stent, said shaft, stent, and sheath cooperatively sized so as to allow co-axially receiving said stent between said shaft and said sheath, said shaft having a swellable radially expandable distal tip having a pre-swollen maximum outside diameter and a post-swelling maximum outside diameter, said sheath having a distal region and a distal end, said stent having a distal end and an inside diameter;

positioning said sheath co-axially over said tip and shaft such that said sheath distal end is positioned near said distal tip;

positioning said stent proximally and co-axially over said shaft such that said stent

distal end is disposed near said distal tip and said stent is radially constrained by said sheath distal region; and

swelling said tip such that said tip maximum radial extent increases.

40. A method as recited in claim 39, wherein said tip is formed of a swellable polymer selected from the group consisting of hydrogels, urethanes, and silicones and said swelling step includes exposing said polymer tip to a solvent selected from the group consisting of water, isopropyl alcohol, heptane, xylene, and toluene.

41. A loaded, self-expanding stent delivery catheter assembly comprising:

a shaft having a distal end, a distal region, and a threaded distal region;

a retractable sheath having a distal region and a distal end disposed co-axially over said shaft distal region such that said sheath distal end is positioned proximally of said shaft distal end;

a self-expanding tubular stent co-axially disposed over said shaft distal region and disposed co-axially within said sheath distal region, such that said stent is radially constrained by said sheath distal region; and

a swollen tip affixed to said shaft distal region.

42. A catheter assembly as recited in claim 41, wherein said distal tip has an swollen maximum radial extent at least as large as the maximum radial extent of said sheath distal region, wherein said distal tip has a pre-swollen maximum radial extent less than the inside diameter of said retractable sheath.

43. A catheter assembly as recited in claim 42, wherein said tip includes a swollen polymer selected from the group consisting of hydrogels, urethanes, and silicones.

44. A catheter comprising:  
an elongate shaft having a distal end; and  
a distal tip secured to said shaft distal end with a shrunken film extending over said tip and shaft distal end.

45. A catheter comprising:  
an elongate shaft having a distal region, a distal end, and radially outward projections extending from said shaft distal region; and  
a distal tip having a body with a lumen therethrough,  
wherein said distal tip is disposed over said shaft distal region and is secured at least in part to said shaft by said outward projections extending into said tip body.

46. A method for assembling a catheter comprising:  
providing an elongate catheter shaft;  
providing a catheter tip having a lumen therethrough;  
providing a solvent capable of swelling said tip;  
swelling said tip with said solvent;;  
co-axially disposing said tip over said shaft distal region; and  
removing said solvent from said tip and allowing said tip to shrink over said shaft



distal region,

wherein said tip lumen prior to swelling is not large enough to allow said shaft to pass into said lumen.

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